RECORD AND BRIEFS

No. 15-1039

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In The

Supreme Court of the United States

SANDOZ INC., PETITIONER,

v.

AMGEN INC. AND
AMGEN MANUFACTURING LIMITED.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

Until this Court intervenes, the Federal Circuit's decision will delay patient access to every biosimilar for at least six months after the biosimilar has been approved by the Food and Drug Administration ("FDA"). Amgen does not deny that is the effect of the Federal Circuit's ruling. Under the court of appeals' erroneous interpretation of 42 U.S.C. § 262(*l*)(8)(A), a biosimilar applicant cannot provide notice of commercial marketing until *after* FDA approval—and a reference product sponsor can obtain a federal injunction barring commercial marketing until 180 days after that notice.

Too much is at stake to accede to Amgen's plea to postpone review. The length of the twelve-year exclusivity period in the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was a hard-fought compromise. By adding six more months of extra-statutory exclusivity, the Federal Circuit has disrupted the balance struck by Congress. This case presents the only foreseeable vehicle to restore that balance. Amgen points to no other case likely to present the question whether the notice of commercial marketing can be given before FDA approval. Nor is there one: as Amgen does not dispute, the Federal Circuit's ruling on this issue binds the nation.

And that ruling is wrong. The plain text of the statute provides that *marketing* must await FDA approval, not that the *notice* of marketing must do so. The

Federal Circuit compounded its erroneous interpretation by turning the BPCIA's mere notice provision into a federal right of action for an automatic 180-day injunction against marketing. While Amgen questions whether the Federal Circuit created such a right, that is the only possible explanation for the court's injunction—in fact, the court held Amgen's state law claim moot because it already had determined to grant an injunction directly under the BPCIA.

ARGUMENT

A. The Questions Presented By Sandoz's Petition Are Important And Warrant This Court's Review Now

This Court's intervention is urgently needed because the Federal Circuit's ruling will necessarily delay the market entry of *every* approved biosimilar, thus thwarting Congress's goal of making less-expensive biologics available to patients and payors.

As the Chairwoman of the Federal Trade Commission ("FTC") has explained, "biologic medicines are among the most important pharmaceuticals available today, providing life-saving therapies for difficult-to-treat diseases such as cancer, diabetes and multiple sclerosis. They are also among the most expensive, with costs often exceeding tens of thousands of dollars per year." FTC, *Follow-On Biologics Workshop*, Tr. 8 (Feb. 4, 2014) (statement of Edith Ramirez).[1] "Introducing

[1] https://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf.

competition into the biologics market place represents one of the most promising ways to reduce prices and expand access to these critical drugs." *Id.* at 8-9.

As the petition explained (Pet. 27-31), the BPCIA therefore struck a balance between competition and innovation by ensuring biologic drug sponsors a twelve-year period of exclusivity from biosimilar competition, to be extended only in expressly defined circumstances. 42 U.S.C. § 262(k)(7)(A); *id.* § 262(m)(2)(A) (adding six months' exclusivity for successful pediatric studies). As explained by one of Sandoz's several amici, the length of the exclusivity period "was a particularly hard-fought piece" of the BPCIA. Biosimilars Council Br. 6. The Federal Circuit's ruling disrupts that statutory balance: it gives sponsors six more months of "extra-statutory exclusivity." Pet. App. 44a (Chen, J., dissenting). Although Amgen quibbles with calling those additional six months "exclusivity" (Opp. 23-25), it does not deny that the ruling means that no biosimilar can launch until at least six months after FDA approval, necessarily granting every reference product twelve-*and-a-half* years without any competing biosimilar on the market.[2]

Amgen agrees that "the BPCIA is an important new statute, and that its proper interpretation is an

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[2] Amgen points to competition from Granix®, a biologic approved under the more onerous, pre-BPCIA approval process in subsection (a). *See* Opp. 23-25. That says nothing about the balance Congress struck with respect to the BPCIA's subsection (k) biosimilar process.

issue of great importance to innovative biopharmaceutical companies, to those who would propose to make biosimilar versions of those innovators' products, and to the public." Opp. 31. Nevertheless, Amgen tells this Court to wait. Opp. 31-36.

But no good reason exists to defer review. This case presents the *only* foreseeable vehicle to decide whether applicants must await FDA approval before providing notice of commercial marketing. As Amgen acknowledges, "there cannot be a split in the circuit courts here" because "the Federal Circuit's jurisdiction is exclusive in actions arising under the BPCIA." Opp. 32. Future Federal Circuit panels and district courts are bound by this decision. The pending appeal in *Amgen Inc. v. Apotex Inc.* (Opp. 4, 33) does not present the timing issue, and Amgen does not contend otherwise.

In any event, to the extent decisions in pending cases might assist this Court, the Court is likely to have the benefit of at least some of them when it considers the merits here. Moreover, many of the questions being litigated in lower courts would be obviated if this Court were to hold that notice can precede FDA approval.

Contrary to Amgen's suggestion (Opp. 35-36), there is tremendous urgency. Granting certiorari now could prevent delay in market entry for dozens of potential biosimilars in the near term: as of December 2015, seven biosimilar applications were pending at the FDA, and at least thirty-three additional biosimilars were in the last phase of pre-application clinical

trials. IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.* 24 (2016).[3]

The potential cost savings to patients and payors (including the federal government) from competing biosimilars are enormous. Although Amgen asserts that "Sandoz is pricing ZARXIO® at only a 15% discount" (Opp. 36), a 15% discount on the $92 billion spent on biologics in 2013 (Biosimilars Council Br. 4) would have been a $13.8 billion savings. And the FTC concluded that 10%-30% biosimilar discounts would deliver "substantial consumer savings." FTC, *Emerging Healthcare Issues: Follow-On Biologic Drug Competition* v (June 2009);[4] *accord* FTC Staff Comment in Response to FDA Request for Comments 5, FDA Docket No. FDA-2013-D-1543 (2015).[5]

B. The Federal Circuit's Ruling Regarding The Notice Of Commercial Marketing Provision Is Wrong

This Court's intervention also is needed because the Federal Circuit added an extra-textual requirement to the statute and then added its own federal injunctive remedy to enforce its invented requirement.

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[3] http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020.

[4] https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report.

[5] https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf.

As Sandoz explained (Pet. 23-27), subsection (*l*)(8)(A) calls only for the applicant to provide notice to the sponsor "180 days before the date of the first commercial marketing" of its biosimilar. 42 U.S.C. § 262(*l*)(8)(A). Nothing mandates that the notice come after FDA approval. Had Congress intended notice to be provided *after* FDA approval and 180 days *before* commercial marketing, it would have said so directly. Pet. 23.

As the petition also explained (Pet. 31-37), the Federal Circuit went on to devise its own federal remedy: an automatic injunction barring the marketing of an approved biosimilar until 180 days after post-approval notice. That creation of an extra-statutory remedy cannot be reconciled with this Court's decisions or those of other circuits. Pet. 31-32. Congress expressly provided a different remedy: the sponsor's right to bring a declaratory judgment action for patent infringement and a bar on a declaratory judgment suit by the applicant. 42 U.S.C. § 262(*l*)(9)(B).

1. Amgen's arguments about the notice provision can be addressed at the merits stage

Amgen makes a series of arguments about the interpretation of subsection (*l*)(8)(A)—all of which can be addressed at the merits stage and are wrong in any event.

Contrary to Amgen's suggestion (Opp. 16-18), the word "licensed" in the phrase "the biological product licensed under subsection (k)" does not suggest that licensure must precede notice. "[L]icensed" in this

phrase is not "the past tense of a verb" (Opp. 17); it is an adjective describing "product." As the district court correctly explained, "'licensed' refers only to 'biological product'"—which necessarily will be licensed by the time of marketing—"not the appropriate time for notice." Pet. App. 75a. That phrase simply identifies the biological product whose commercial marketing is relevant to measuring the 180-day period. Pet. 24.

Amgen also argues that if subsection (*l*)(8)(A) were referring to a not-yet-approved product, Congress would have used the phrase "the biological product that is the subject of the subsection (k) application" to identify the product whose commercial marketing measures the 180-day period. Opp. 17 (quotation marks omitted). But if Congress had used that phrase to identify the product, that might have suggested notice could be given *only* before approval. Instead, the text of subsection (*l*)(8)(A) does not measure the timing of the notice by the date of FDA approval at all; the timing is measured only by "the date of the first commercial marketing." 42 U.S.C. § 262(*l*)(8)(A).

Noting that the term "subsection (k) applicant" is defined as "a person that submits an application under subsection (k)," *id.* § 262(*l*)(1)(A), Amgen argues that the notice provision's use of that term does not matter because an applicant remains "the subsection (k) applicant" even after approval. Opp. 22. But if Congress meant to mandate that notice be given only after approval, it would not have used "applicant" at all. Instead, it would have referred to the "holder" of an approved application, as it did elsewhere. *See* 42 U.S.C.

§ 262(m)(3). By using "subsection (k) applicant," Congress made clear that notice can be given *before or after* approval because (as Amgen acknowledges) an applicant is a "subsection (k) applicant" both before and after.

Turning to policy arguments, Amgen suggests that the notice should come after approval because of the "possibility of changes in the product or its uses" between application and approval. Opp. 20. But that rationale contradicts a central purpose of the BPCIA: facilitating resolution of patent disputes before approval. This purpose is fulfilled only if notice can be provided before approval. Pre-BPCIA law already provided a way to resolve patent disputes after licensure, or even when licensure was imminent: a declaratory judgment suit for infringement under 35 U.S.C. § 271(a) and/or (g). Pet. 26-27. The BPCIA created "artificial" acts of infringement precisely so litigation could occur *before* any imminent infringement.

Next, trying to make sense of requiring "notice" after the public act of licensure, Amgen asserts that the purpose of notice is "so that the Sponsor will know *when* the Applicant will commence marketing" because "[i]t cannot be presumed that commercial marketing will always follow 180 days after approval." Opp. 22. But even under Amgen's interpretation, the applicant is not required to definitively state when it will market; subsection (*l*)(8)(A) calls simply for notice that marketing will begin *at least* 180 days later.

None of Amgen's other merits arguments on the minutiae of the statute is reason to deny review. First, the separate "interchangeability" provisions of the BPCIA have nothing to do with whether notice can be provided before approval. *Contra* Opp. 18-19. Second, Sandoz's reading would not render "meaningless" the stay provision in subsection (*l*)(9)(A). *Contra* Opp. 19. That provision provides a stay in all situations where there is time between an applicant's disclosure of its biosimilar application and its notice of commercial marketing. In the specific fact pattern posited by Amgen—where an applicant gives notice as soon as it files its application—the applicant simply forgoes the benefits of the stay. But the applicant still provides notice, thus triggering the sponsor's ability to sue on all its patents. Third, Amgen suggests that under Sandoz's reading, the supposed "180-day period" during which the sponsor can "mov[e] for a preliminary injunction" under subsection (*l*)(8)(B) might elapse before identifying the patents on which an injunction could be sought. Opp. 19. Amgen's premise is mistaken. Subsection (*l*)(8)(B) does not limit a sponsor to 180 days to seek an injunction; it allows the sponsor to do so at any time after notice and before marketing. 42 U.S.C. § 262(*l*)(8)(B).

2. *Contrary to Amgen's assertions, the Federal Circuit ruled on the questions presented in Sandoz's petition*

Amgen makes no effort to grapple with decisions from this Court and other courts of appeals rejecting extra-textual private rights of action and remedies,

such as the injunctive remedy under the BPCIA created by the Federal Circuit. *See* Pet. 31-35. Instead, Amgen raises purported vehicle issues, noting that it sued to enforce its reading of the BPCIA only through state law causes of action, without claiming an implied federal cause of action. Opp. 28.

But the Federal Circuit's decision makes clear that its injunction was not based on state law. The Federal Circuit held that Amgen's appeal of the dismissal of its California claim based on Sandoz's notice was "moot" precisely because the court of appeals already had determined to grant Amgen federal injunctive relief based directly on the BPCIA. Pet. App. 27a-28a. As the Federal Circuit explained, it granted an injunction through September 2, 2015 (180 days after Sandoz's post-approval notice) "[i]n light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA." Pet. App. 31a. That this injunction was based on a newly minted federal action directly under the BPCIA is confirmed by the injunction's nationwide scope. A California cause of action could have supported an injunction only as to "conduct occurring within California." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1360 (Fed. Cir. 2013).

Amgen argues that, rather than fashioning a new remedy, the Federal Circuit granted an injunction pending appeal under Rule 8(a) of the Federal Rules of Appellate Procedure. Opp. 29-31. Although the court granted such an injunction when the case was first appealed (CAFC Dkt. No. 105), Rule 8 was not (and could

not have been) the basis of the injunction created by its ultimate decision. That injunction was not one that lasted "pending" the appeal; to the contrary, the court "extend[ed]" the injunction only to a particular date, September 2, 2015, based on its judgment on the merits. Pet. App. 28a. In fact, the Federal Circuit denied Amgen's request for an injunction pending consideration of en banc review. CAFC Dkt. No. 128.

Contrary to its position in this Court, Amgen has recognized elsewhere that the Federal Circuit's injunction was based directly on the BPCIA, not Rule 8. In urging this Court to defer consideration of the question whether there is a private right of action under the BPCIA, Amgen points to another case it has filed. Opp. 29. Amgen told the district court in that case that the Federal Circuit's decision *in this case* held that a private right of action exists under the BPCIA: "As in *Amgen*, a private cause of action must exist to permit the Court to enforce the statute." Pls.' Answering Br. in Opp. to Def.'s Mot. to Dismiss 9, *Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-00839-RGA (D. Del. Dec. 3, 2015), ECF No. 17. There, Amgen contended that to conclude otherwise "would be at odds with *Amgen*, where the Federal Circuit entered injunctive relief against Sandoz." *Ibid.*

That Amgen did not itself press for an implied federal right of action here is therefore of no moment for present purposes. The Federal Circuit necessarily decided there was such a right, thus squarely presenting

the issue for this Court's review. *United States v. Williams*, 504 U.S. 36, 41 (1992) (issue reviewable if "not pressed so long as it has been passed upon").[6]

Amgen also argues that because Sandoz provided a second notice after FDA approval, this case does not present the question whether subsection (*l*)(9)(B) "is the exclusive remedy available to a Sponsor where an Applicant fails to give timely notice of commercial marketing." Opp. 27. But that provision covers both when the applicant gives no notice and when it gives notice and launches fewer than 180 days after doing so: in either situation, the applicant has "fail[ed] to complete an action required of the subsection (k) applicant under * * * paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(B). And again, Amgen is telling another court something different than it is telling this Court. In a pending Federal Circuit appeal, in which the applicant Apotex has given *no* notice, Amgen contends that the decision in this case governs that fact pattern—"the majority held in *Amgen v. Sandoz*: the [sponsor] is not *required* to bring a declaratory-judgment action" under subsection (*l*)(9)(B)." Amgen Br. 47-48, *Amgen Inc. v. Apotex Inc.*, No. 16-1308 (Fed. Cir. Feb. 4, 2016), ECF No. 67; *see id.* at 56.

Finally, contrary to Amgen's suggestion (Opp. 30), Sandoz's second notice did not "commit[] not to do" anything; it was expressly "without prejudice" to Sandoz's

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[6] By contrast, with respect to the issue presented by Amgen's conditional cross-petition, the question of a federal right of action and remedy was neither pressed *nor* passed on. *See* 15-1195 Sandoz Opp. 24-34.

positions in this litigation (CA JA A1774). Sandoz has consistently contested the propriety of *any* injunction to compel compliance with the terms of the notice provision, contending that the BPCIA provides other consequences for not following its terms. *E.g.*, Sandoz CA Br. 46-54; Sandoz CA Reh'g Pet. 10-14.[7] Because the BPCIA expressly provided remedies, the Federal Circuit should not have created its own. *Karahalios v. Nat'l Fed'n of Fed. Emps.*, 489 U.S. 527, 533 (1989).

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[7] Amgen's oral argument quotation (Opp. 30) omits the end of Sandoz's counsel's sentence—"under their theories"—which made clear she was simply noting the "outside date" an injunction could last under *Amgen's* position. CA Oral Arg. 35:42-35:55, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1499.mp3. Later, Sandoz's counsel emphasized that, except for the confidentiality provision in subsection (*l*)(1)(H), "Congress provided no remedies to compel any step. Instead, it said if they aren't followed, you go immediately to the patent infringement suit." *Id.* at 42:19-42:28.

CONCLUSION

For all these reasons and those in Sandoz's petition, the petition should be granted.

Respectfully submitted,

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